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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,472	07/02/2003	Frederick M. Ausubel	00786/254004	5312

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EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,472	AUSUBEL ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11 and 15* is/are rejected.

7)☒ Claim(s) *8-10 and 12-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-4 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying plant disease resistance genes comprising introducing a candidate gene into a plant via biolistic transformation and assaying the plant for disease resistance, does not reasonably provide enablement for a method of identifying plant disease resistance genes comprising introducing candidate genes from cDNA libraries into a plant tissue via biolistic transformation and assaying the plant tissue for disease resistance is withdrawn in light of Applicant's amendment of the claims and Applicant's arguments.

Claim Rejections - 35 USC § 112

4. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to a specific bacterial strain. Since the strain is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the strain is not so obtainable or available, a deposit of strain may satisfy the requirements of 35 USC 112. The specification does not

disclose a repeatable process to obtain the strain and it is not apparent if the strain is readily available to the public. Thus, a deposit is required for enablement purposes.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.801 - 1.809 [MPEP 2401-2411.05] for additional explanation of these requirements.

Claim Rejections - 35 USC § 102

5. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Keen et al (1993, Biotechnology in Plant Disease Control (Chet, ed.), pg 65-88). The rejection is repeated for the reasons of record as set forth in the Office action mailed 22 December 2004. Applicant's arguments filed 24 June 2005 have been fully considered but they are not persuasive.

Keen et al disclose a method of identifying plant disease resistance genes comprising introducing candidate genes from cDNA libraries into a plant via biolistic transformation and

assaying the plant for disease resistance (pg 79, paragraph 4, to pg 82, paragraph 1). The plant would comprise leaves, roots and stems and at certain points in its life would comprise flowers and fruit. The assayed disease resistance response is the hypersensitive response (pg 80, paragraph 1; pg 81, paragraph 2).

Applicant urges that Keen does not use a plant tissue sample that includes a mutant disease resistance gene (response pg 9-10).

This is not found persuasive because Keen uses plant lines lacking the resistance gene; these lines would have null mutant genes (pg 79, paragraph 4). Keen uses plant tissues as the plant source (pg 80, paragraph 3)

Claim Rejections - 35 USC § 103

6. Claims 1-2 rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes et al (1993, Plant Science 89:43-53) in view of Daniell et al (US Patent 5,693,507, filed at least January 1991). The rejection is repeated for the reasons of record as set forth in the Office action mailed 22 December 2004. Applicant's arguments filed 24 June 2005 have been fully considered but they are not persuasive.

The claims are drawn to a method of identifying plant disease resistance genes comprising introducing a candidate genes into a plant via biolistic transformation and assaying the plant for disease resistance.

Jaynes et al disclose a method of identifying genes that confer disease resistance on a plant, wherein the method comprises introducing a candidate gene encoding cecropin B into a

tobacco plant via Agrobacterium transformation and assaying the plant for disease resistance (pg pg 48-50). Jaynes et al do not disclose use of biolistic transformation in the method.

Daniell et al teach biolistic transformation of tobacco (column 11, lines 55-65)

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of identifying genes that confer disease resistance as taught by Jaynes et al, to introduce the gene via biolistic transformation as described in Daniell et al. One of ordinary skill in the art would have been motivated to do so because selection of one transformation over another is an obvious design choice.

Applicant urges that the claims have been amended to use plant tissue sample that includes a mutant disease resistance gene (response pg 10).

This is not found persuasive because all plants contain null mutations of disease resistance genes.

7. Claims 1-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen et al (1993, Biotechnology in Plant Disease Control (Chet, ed.), pg 65-88).

The claims are drawn to a method of identifying plant disease resistance genes comprising introducing a candidate genes into a plant via biolistic transformation and assaying the plant for disease resistance.

The teachings of Keen are discussed above. Keen does not disclose using leaf tissue as the plant tissue sample or infiltrating with Pseudominas syringae.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of identifying plant disease resistance genes as taught by Keen, to

use leaf tissue as the plant tissue sample or infiltrating with Pseudominas syringae. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Keen to use any plant part that exhibits the correct host-pathogen specificity (pg 81, paragraph 2); as leaves are the tissue that are commonly affected, one of skill in the art would use leaves. The side of the leaf not treated with the bacteria would act as the control. One of skill in the art would have been motivated to use Pseudominas syringae because that is the source of avrD suggested for use by Keen (pg 80, paragraph 2).

8. Claims 8-10 and 12-15 are free of the prior art, given the failure of the prior art to teach or suggest a method of identifying plant disease resistance genes comprising introducing a candidate genes and a reporter gene into a plant via biolistic transformation and assaying the plant for disease resistance.

9. Claims 8-10 and 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
September 13, 2005

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER